



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

SEP 24 1998

Ms. Betty Lane
Director of Quality and
Regulatory Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02154

Dear Ms. Lane:

This is in response to your letter of September 21, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your submission states that Selfcare, Inc. is making claims for the product SoyCare for Menopause, that the product is, among other things, intended to provide menopausal symptom relief, reduce hot flashes and night sweats, protect against the risk of certain disease (i.e., cardiovascular disease and osteoporosis), and be safe alternative to hormone replacement therapy.

Your submission also states that Selfcare, Inc. is making claims for the product SoyCare Bone Health that the product is, among other things, intended to reduce some menopausal symptoms and be a safe alternative to hormone replacement therapy for bone mass loss

Your submission also states that Selfcare, Inc. is using citations to one or more articles or other sources, some of which (for example; Paola Albertazzi et al, *The Effect of Dietary Soy Supplementation on Hot Flashes*, Obstet Gynecol; 1998; 91:6-11) appear to suggest that the products are intended to treat, prevent, mitigate, or cure disease.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, mitigate, or prevent disease or are intended as alternatives to approved therapies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 225

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New England District Office, Compliance Branch, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file, OSN#61356)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:rjm:HFS-456:9/24/98:61356.adv:disc32

Selfcare, Inc.

200 Prospect Street
Waltham, Massachusetts 02154

Telephone 781-647-3900
Facsimile 781-647-3939

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RECEIVED
9/24/98

September 21, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Sir or Madam:

This notification is being made, as required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, that Selfcare, Inc. intends to market dietary supplements products with the following labeling statements of nutritional support:

SoyCare for Menopause

- Reduces Hot Flashes & Night Sweats. Studies have shown that the use of soy isoflavones can reduce hot flashes and night sweats by 33% in frequency over a four-week period¹, and 53% in intensity over a twelve week period². SoyCare™ gives you a concentrated amount of soy isoflavones, so that you only need to take one capsule in the morning and one before bed, to help alleviate the discomfort and aggravation of hot flashes and night sweats.

¹ Paola Albertazzi et al, *The Effect of Dietary Soy Supplementation on Hot Flashes*, Obstet Gynecol; 1998; 91: 6-11.

² Ammon Brezinski et al, *Short-term Effects of Phytoestrogen-rich Diet on Postmenopausal Women*, Menopause; 1997, Vol. 4, No. 2 pp. 89-94.

- For Menopausal Symptom relief, without hormonal side effects. As you mature, your production of hormones slows down, which can result in hot flashes, vaginal dryness, and a greater risk of cardiovascular disease and bone density loss. Soy isoflavones are a natural plant hormone (phytoestrogen) that help you to reduce the everyday symptoms of menopause, while protecting your body from other risk factors. Studies have shown that soy isoflavones deliver benefits similar to hormone replacement therapy.

- (Picture of two SoyCare products) Congratulations! You've just made an important step toward reducing some menopausal symptoms and maintaining your healthy bones.
- SoyCare for Menopause. The Natural Plant Estrogen for Menopausal Symptom Relief.
- For women who don't choose HRT, SoyCare for Menopause is a safe, natural supplement that helps reduce hot flashes and night sweats. SoyCare™ contains concentrated soy-isoflavones (plant estrogens), which scientific studies have shown to reduce the frequency of hot flashes and night sweats by 33% over a 4-week period¹. Studies have also shown a reduction in the intensity of these symptoms by 53% over a 12-week period², with no hormonal side effects. Because SoyCare contains such a concentrated amount of soy-isoflavones, you only need to take two capsules per day: one in the morning and one at bedtime, or as recommended by your physician.
- Plant Estrogens, Without Hormonal Side Effects
- SoyCare mimics the intake of an Asian soy-rich diet, known to coincide with fewer hot flashes and night sweats, healthier bones and greater cardiovascular health.
- Reduces hot flashes and night sweats.
- A safe alternative to Hormone Replacement Therapy for reducing hot flashes and night sweats, with no hormonal side effects.
- Includes soy protein to help maximize the effects of Isoflavones, for a more effective reduction of hot flashes.

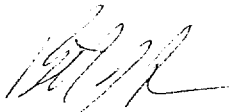
SoyCare Bone Health

- Dual Action! Helps Build Plus Retain Calcium For Healthy Bones
- Isoflavones are a natural plant hormone (phytoestrogen) that help your body to retain bone mass. In addition, isoflavones help you to better incorporate the calcium you take - and each tablet of SoyCare for Bone Health contains 300 mg of supplemental calcium. Studies have shown that isoflavones deliver benefits similar to hormone replacement therapy for maintaining bone mass, but without the risk of hormonal side effects.
- Dual action Formula
Enriched with calcium and Vitamin D ⇒ Helps your body build and absorb your calcium supply
Concentrated Soy Isoflavones ⇒ Helps to retain calcium already in your bones
- (Picture of two SoyCare products) Congratulations! You've just made an important step toward reducing some menopausal symptoms and maintaining your healthy bones.
- SoyCare has a unique Dual-Action Formula: it Builds plus Retains calcium in your bones.
- Three essential elements are included in our Dual-Action Formula
 - 300 mg of calcium to build bone
 - Vitamin D to assist in calcium absorption
 - Soy-isoflavones, which stimulate bone-building cells to utilize and retain calcium

- SoyCare mimics the intake of an Asian soy-rich diet, known to coincide with fewer hot flashes and night sweats, healthier bones and greater cardiovascular health.
- Unique Dual Action!: Helps Build Plus Retain Calcium
- Triple Element Formula; Soy Isoflavones + Calcium 300mg + Vitamin D - For the bone health benefits of soy, no gas distress and enhanced calcium absorption into the blood stream.

If you have any questions regarding this information please feel free to contact me at (781) 647-3900 x144.

Sincerely,

A handwritten signature in black ink, appearing to read 'Betty Lane', with a stylized, cursive script.

Betty Lane
Director of Quality and Regulatory Affairs
Selfcare, Inc.